December 19, 2025

CatheGenix (Xiamen) Co., Ltd.
Deyuan Zheng
Management representative
Room 605-2A, No.37 Banshang, Building 2, Torch Hi-Tech Zone
Xiamen, Fujian 361000
CHINA

Re: K251469
Trade/Device Name: Endura™ Ureteral Stent and Stent Set
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: November 21, 2025
Received: November 21, 2025

Dear Deyuan Zheng:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JESSICA K. NGUYEN -S

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive, Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K251469 |

Please provide the device trade name(s).

Endura™ Ureteral Stent and Stent Set

Please provide your Indications for Use below.

The device is indicated to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions in the ureter. The stent may be placed using endoscopic surgical techniques or percutaneously using standard radiographic techniques. It is recommended that the indwelling time not exceed 365 days. The stent is not intended as a permanent indwelling device.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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**510(k) Summary**

## 1. Submitter's Information

Sponsor: CatheGenix (Xiamen) Co., Ltd.
Room 605-2A, No.37 Banshang, Building 2, Torch Hi-Tech Zone, Xiamen 361000, P.R. China

Contact: Deyuan Zheng
CatheGenix (Xiamen) Co., Ltd.
Management representative
86+15201818268

Date Prepared: December 18, 2025

## 2. Identification of Proposed Device

| | |
|---|---|
| Trade Name: | Bard® InLay Optima™ Ureteral Stent |
| Common Name: | Stent, Ureteral |
| Review Panel: | Gastroenterology/Urology |
| Classification Regulation: | 21 CFR 876.4620 |
| Product Code: | FAD |
| Device Class: | 2 |

## 3. Identification of Predicate Devices

Bard® InLay Optima™ Ureteral Stent cleared under K022447.

## 4. Intended Use/Indications for Use

The device is indicated to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions in the ureter. The stent may be placed using endoscopic surgical techniques or percutaneously using standard radiographic techniques. It is recommended that the indwelling time not exceed 365 days. The stent is not intended as a permanent indwelling device.

## 5. Device Description

The subject devices are coated ureteral stent that are supplied as a standalone product (including a pigtail straightener) or as part of a set, available in two configurations: Basic Set and Full Set.

- Basic Set: Includes a ureteral stent, pigtail straightener, and positioner.
- Full Set: Includes a ureteral stent, pigtail straightener, positioner, and J-tip guide wire.

The coated stents are flexible tubular devices made of radiopaque polyurethane, featuring self-retaining coiled pigtail structures at both ends. The stent body incorporates multiple drainage holes to ensure smooth urine flow from the renal pelvis

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to the bladder. The dual-pigtail design positions the proximal end in the renal pelvis and the distal end in the bladder. Additionally, the stent surface is marked with graduated scales for precise intraoperative positioning.

## 6. Comparison to Predicate Devices

The subject device is substantially equivalent to the predicate devices as they share the same indications for use and similar technological characteristics. Technological characteristics of the subject device compared to each predicate is shown in the following table.

Table 1. General Comparison

| **Technological Characteristics** | **Proposed Device** | **Predicate Device** Bard® InLay Optima™ Ureteral Stent**[K022447]** |
|---|---|---|
| Manufacturer | CatheGenix (Xiamen) Co., Ltd. | C. R. Bard, Inc. |
| Regulation Number | 21 CFR 876.4620 | 21 CFR 876.4620 |
| Product Code | FAD | FAD |
| Classification Name | Stent, Ureteral | Stent, Ureteral |
| Classification | CLASS II | CLASS II |
| Intended Use /Indications for Use | The device is indicated to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions in the ureter. The stent may be placed using endoscopic surgical techniques or percutaneously using standard radiographic techniques. It is recommended that the indwelling time not exceed 365 days. The stent is not intended as a permanent indwelling device. | The Bard® InLay Optima™ Ureteral Stent is indicated to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions in the ureter. These conditions include stones and/or stone fragments or other ureteral obstructions such as those associated with ureteral stricture, malignancy of abdominal organs, retroperitoneal fibrosis, or ureteral trauma, or in association with Extracorporeal Shock Wave Lithotripsy (ESWL). The stent may be placed using endoscopic surgical techniques or percutaneously using standard radiographic techniques. It is recommended that the indwelling |

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| | | |
|---|---|---|
| | | time not exceed 365 days. The stent is not intended as a permanent indwelling device. |
| Structure and Design | The ureteral stent features a double-pigtail design with drainage holes | The ureteral stent incorporates a double-pigtail design with drainage holes plus a distal suture thread. |
| Fr, Size Available | 4.5Fr, 4.7Fr, 6Fr, 7Fr, 8Fr, 8.5Fr, 10Fr | 4.7Fr, 6Fr, 7Fr, 8Fr |
| Length | 18cm, 20cm, 22cm, 24cm, 26cm, 28cm, 30cm | 14, 20-30cm |
| Materials | Thermoplastic polyurethane (TPU) | TPU |
| Package | Single-use EO sterilized pouch with one device per pouch | Single-use EO sterilized pouch with one device per pouch |
| Sterility | Yes, $10^{-6}$ | Yes, $10^{-6}$ |
| Sterilization method | EtO sterilized | EtO sterilized |
| Single Use | Yes | Yes |

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## 7. Summary of Non-Clinical Performance Data

Bench testing was performed to establish substantial equivalence to the predicates and to demonstrate that the subject device will perform as intended. Testing was conducted in accordance with FDA guidance document *Guidance for the Content of Premarket Notifications for Ureteral Stents* (February 1993). All the testing results meet the defined acceptance criteria. Detailed testing conducted are as follows:

- Appearance and Dimensions
- Anti-encrustation Performance Test
- Compatibility Performance Test
- Radiopacity Performance Test per ASTM F1828-22
- Elongation and Tensile Strength Performance Test per ASTM F1828-22
- Flow Rate Performance Test per ASTM F623-19
- Curl Strength Performance Test per ASTM F1828-22

Sterilization validation of Endura™ Ureteral Stent and Stent Set was carried out in accordance with ISO 11135:2014+A1:2018 "Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices".

Packaging & Shelf-life testing was conducted based on an accelerated aging test in accordance with:

- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO 11607-1:2019: Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019: Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F88/F88M-23 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F1140/F1140M-13(Reapproved 2020)e1 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages

Accelerated aging test was performed to demonstrate the device's stability during its

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claimed shelf life.

Biocompatibility evaluation for the Endura™ Ureteral Stent and Stent Set was conducted in accordance with FDA Guidance, Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process" (September 8, 2023), the following tests were conducted:

a) Cytotoxicity

b) Sensitization

c) Irritation

d) Acute System Toxicity

e) Pyrogen

f) Implantation

g) A chemical analysis on the device extractables and a toxicological risk assessment on the identified extractables compounds performed to address subacute/subchronic toxicity, genotoxicity, chronic toxicity and carcinogenicity.

## 8. Summary of Clinical Test

No clinical study is included in this submission.

## 9. Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the Endura™ Ureteral Stent and Stent Set has been shown to be appropriate for its intended use and is substantially equivalent to the predicate device.